T.13013/01/2018-Imm
Government of India
Ministry of Health & Family Welfare
Immunization Division

Nirman Bhawan, New Delhi
Dated: 11th September 2023

To,

All NTAGI members/Participants
(As per list enclosed)

Subject: Minutes of the meeting of 18th National Technical Advisory Group on Immunization (NTAGI) held on 26th July 2023, under the Chairpersonship of Secretary, Health and Family Welfare (HFW) at Nirman Bhawan, New Delhi. .

Sir/Madam,

Please find enclosed herewith the minutes of the meeting of 18th National Technical Advisory Group on Immunization (NTAGI) held on 26th July 2023 under the **Chairpersonship of Secretary, Health and Family Welfare (HFW) at Nirman Bhawan, New Delhi, for your kind perusal.**

Yours faithfully,

14/9/23

Enclosure: as above

Dr. Veena Dhawan
Additional Commissioner (UIP)

Copy to:

1. Sr. PPS to Secretary (H&FW), MoHFW
2. PPS to DGHS, MoHFW
3. PPS to Secretary, Department of Health Research (DHR), MoHFW
4. PPS to Secretary, Department of Biotechnology (DBT), MoS&T
5. PPS to AS&MD (NHM), MoHFW
6. PPS to JS (RCH), MoHFW
7. Office Copy

18TH NATIONAL TECHNICAL ADVISORY GROUP ON IMMUNIZATION(NTAGI) MEETING

Minutes of the Meeting

26 JULY' 2023, WEDNESDAY

Nirman Bhawan, Delhi

18th meeting of National Technical Advisory Group on Immunization

26th July 2023

Minutes of the Meeting

1.0 Welcome & Introduction

The 18th NTAGI meeting was held on Wednesday, July 26th, 2023 at MoHFW, Nirman Bhawan, New Delhi, under the Chairpersonship of Shri Rajesh Bhushan, Secretary Health & Family Welfare (H&FW) and co-chairpersonship of Dr. Rajiv Bahl, Secretary, Department of Health Research & Director General, Indian Council of Medical Research (ICMR).
The participating NTAGI members had duly filled and signed the confidentiality- cum-declaration form and shared with the NTAGI Secretariat. No significant conflict of interest was observed in the forms received. The Chairperson was appraised about the recently conducted 45th NTAGI-STSC meeting, held under the co-chairpersonship of Dr. Rajesh Gokhale. Secretary, Department of Biotechnology (DBT) and Dr. Rajiv Bahl, Secretary, Department of Health Research & Director General, Indian Council of Medical Research (ICMR). The minutes of the 17th NTAGI meeting held on June 28, 2022 were shared with the members. The minutes were formally confirmed by the NTAGI. It was informed that a newly designated member of the NTAGI, Dr. Navin Khanna has resigned from the NTAGI, owing to a conflict of interest in lieu of change of professional role. The list of attendees is Annexed as Annexure-1 and Agenda as Annexure-2.

1.1 Opening Remarks

All participants were welcomed by the Chairperson and Co-Chairpersons, following which the Secretary (H&FW, MoHFW) called the meeting to order. Following agenda items were discussed:

2.0 Agenda Item 1 : Action taken report on 17th NTAGI meeting held on June 28, 2022: JS-RCH , MOHFW

Dr. P. Ashok Babu, Joint Secretary-RCH(MoHFW) informed that the last meeting of the NTAGI was held on 28th June' 2022. The action taken report (ATR) based on the recommendations made in the 17th NTAGI meeting was presented. The following points were discussed:

2.1 Typhoid Conjugate Vaccine

NTAGI Recommendations:

- The NTAGI had observed that indigenous Typhoid conjugate vaccines (TCV) are safe and efficacious, and there is sufficient burden of typhoid in the country to consider it a public health problem. Therefore, it is worthwhile to introduce Typhoid conjugate vaccine in the Universal Immunization Program (UIP).
- Program managers in the Immunization Division may consider one of the recommended strategies on introduction of the Typhoid conjugate vaccines in UIP

2.1.1 Action Taken:

- Typhoid Surveillance Group (TSG) and Typhoid Conjugate Vaccine Operations Group (TOG) have been constituted to facilitate the introduction of TCV in the UIP.
- A qualitative study has been initiated with relevant stakeholders in 8 States to generate scientific evidence on acceptability of administering multiple injectable vaccines in a single visit. Protocol and ethical clearance have been taken. Study findings will be presented in subsequent meetings.

2.2 HPV Vaccine:

NTAGI Recommendations:

- The indigenously developed qHPV vaccine may be considered for introduction in the UIP as a two-dose regimen.
- A cohort study may be conducted to assess the immunogenicity, persistence of immune response, and protection from infection for up to two years after a single dose of indigenously developed qHPV vaccine.
- A mechanism may be developed in the UIP to follow up girls who have received the first dose of HPV vaccine and missed the second dose. Their samples may be collected after two years to assess immunogenicity and effectiveness of single dose vaccine.

2.2.1 Action Taken:

- The introduction of the vaccine has been approved, and MOHFW is currently working on its implementation in the UIP.

2.3 COVID-19 Vaccines

NTAGI Recommendations:

- The working group may review the evidence on requirement of further booster doses of COVID-19 Vaccines in the general population as well as special population groups.
- The CWG/STSC may review evidence from the currently available vaccine options and recently concluded booster studies and recommend appropriate homologous/heterologous booster dose if required.
- The team may be constituted under the leadership of Dr. RS Sharma to work on the harmonization of data from the COVID-19 India portal, ICMR COVID-19 testing portal, and CoWIN. The NTAGI Secretariat may follow up with this newly constituted team and report the progress to STSC and NTAGI.
- Individuals with partial or full vaccination history from abroad may be provided domestically available vaccines as per the recommendations of the 32nd STSC. These individuals may be allowed to upload their vaccine records in the CoWIN portal.

2.3.1 Action Taken:

- The STSC has reviewed data and recommended a single precaution dose of COVID-19 vaccines for individuals aged 60 years and above, and 18-60 year old individuals with comorbidities and immunocompromised conditions. Precautionary dose of COVID-19 vaccine is available to individuals aged 18 years and older.
- The policy question on homologous/heterologous boosters is currently under the consideration of the COVID-19 Working Group of the NTAGI.
- A committee has been formed with ICMR, NCDC and CWG for synchronization of COVID-19 data portals. Two meetings have been conducted, and data has been synergized. The results of the synchronization and impact of vaccination will be shared with the CWG and STSC in subsequent meetings.
- Necessary provisions have been provided for individuals vaccinated abroad, and the same has been communicated to all States/UTs as per the letter number DO No. T-22014/22/2021/Imm.

2.4 Discussion:

The Chairperson opened the floor for discussion after presentation of the Action Taken Report. He cordially invited the members and participants to shed light on the recommendations and proceedings related to the three vaccines discussed in the Action Taken Report - TCV, HPV vaccine, and COVID-19 vaccines.

The discussion was initiated by the Co-Chairperson, as he highlighted the issues faced with the proposed cohort study on the effectiveness of a single dose of indigenous qHPV vaccine. He brought to the notice of the NTAGI that the relevance and necessity of such studies have been questioned by the manufacturer as well as the Subject Expert Committee (SEC) of the Central Drugs Standard Control Organisation (CDSCO). Following deliberation in the SEC meeting by Dr. Nivedita Gupta on behalf of the ICMR, the SEC has recommended a phase 3 efficacy study following a single dose of vaccine. However, a phase 3 efficacy trial for single dose would require substantial time depending on the age groups included in the study for completion. After highlighting the challenges faced with the initiation of the single dose efficacy study of HPV vaccine, DG-ICMR stated that the ICMR is willing to initiate the single dose antibody persistence study Suo-moto to avoid further delays. Another initiative taken by ICMR is to encourage development of urinary HPV antigen testing kits in the country; this will obviate the need for obtaining vaginal swabs for determining the vaccine efficacy and likely to improve the compliance of the process.

The Chairperson, stated that the SEC of CDSCO reviews the data and recommends to the Drug Controller General of India (DCGI), however, the authority of granting licensure rests solely with the DCGI. Therefore, the decision taken by the DCGI may differ from the SEC recommendations. Similarly, the decision on introduction of single/double dose regimen of the vaccine in the UIP is solely at the discretion of the Ministry of Health and Family Welfare.

Dr. N.K Arora stated that there is an inherent conflict of interest on the part of the vaccine manufacturer in conducting a single dose trial of a vaccine that has been developed as a 2-dose series. He also mentioned that none of the approved/licensed HPV vaccines elsewhere

globally are recommended as single dose schedule on-label, and the one-dose recommendation by WHO is strictly off-label and meant for public health programmes.
Dr. Rakesh Aggarwal re-iterated the conflict of interest from the manufacturer, and stressed on the importance of collaboration between the NTAGI/NTAGI Working Groups and SEC of CDSCO, so that a vaccine may also be looked at as a public health tool and not merely a biological product. The NTAGI agreed that ICMR may initiate the single dose study on qHPV vaccine.

3.0 Agenda Item 2: STSC updates and Recommendations: Co-chairperson, STSC

The chairperson announced that co-chairperson, Dr. Rajesh Gokhale, Secretary of DBT was unable to attend the meeting due to his presence in the Parliament. The update on the Standing Technical Sub-Committee (STSC) meetings from July'22- June'23 was presented by the co-chairperson, Dr. Rajiv Bahl, Secretary, DHR and DG-ICMR. It included the 43rd – 45th meetings of the NTAGI-STSC with the following agenda items:

- **43rd NTAGI-STSC (Aug 23, 2022):**
  - Pneumococcal Vaccine for Sickle cell disease Patient
  - Covid-19 Working Group
- **44th NTAGI-STSC (Dec 16 ,2022):**
  - RSV disease Intervention
  - Hexavalent Vaccine Working Group
  - SWG-IVRCB
  - Monkeypox Working Group
  - HPV Working Group
- **45th NTAGI-STSC (June 22, 2023):**
  - SWG-VPD
  - SWG-IVRCB
  - JE Working Group
  - PCV for Sickle Cell Disease Working Group
  - Covid-19 Working Group

3.1 43rd NTAGI-STSC MEETING - The agenda and the discussion points in the STSC meeting were:

3.1.1 Covid-19 Working Group:

- CORBEVAX™ vaccine for heterologous Booster
- GEMCOVAC-19 Vaccine for primary doses
- COVOVAX® vaccine for paediatric population

- BBV154 (Intra-nasal) Vaccine for primary dosing and heterologous/homologous booster
- The CMC Vellore's COVID-19 Vaccine Heterologous/Homologous Booster study
- To improve the quality of vaccine development plans and review process for pre-licensure and post-licensure clinical studies, an inter-agency coordination meeting is warranted.

3.1.2 PCV for Sickle Cell Disease:

- A working group was constituted the chairpersonships of Dr. Satinder Aneja and Dr. NK Arora to deliberate on the pneumococcal vaccine schedule for patients with sickle cell disease. This working group to include members from professional organizations working in the area of hemoglobinopathies.
- In addition to SCD, guidance may be made for other high-risk conditions where pneumococcal vaccines are warranted.
- Guidance for vaccines other than PCV may also be developed
- Incidence of Invasive Pneumococcal Disease among Individuals with Sickle Cell Disease before and after Introduction of Pneumococcal Conjugate Vaccine in USA: 93.4% reduction in under 2 years children
- PCV-13 was introduced in India in 2017 in 35 districts covering eight percent of the birth cohort of the country; In 2021 the PCV-10 vaccine (SII) is rolled out across the entire country. This will positively impact the sickle cell disease carriers and disease subjects particularly in tribal belt with maximum sickle cell gene prevalence.

3.1.3 Discussion

In view of the current state of the pandemic, the MoHFW has decided to discontinue the two percent random samples for Covid-19 testing of the incoming international passengers. The co-chairperson suggested discussion regarding: modality of Covid-19 vaccine booster doses; the relevance of continued capturing of the data on the Co-WIN software and
The co-chairperson informed that the Sickle Cell Working Group was formed following the announcement of the Sickle cell disease being a priority national agenda.

3.2 44th NTAGI-STSC Meeting: The agenda and the discussion points in the STSC meeting were:

3.2.1 RSV Disease:

- The RSV WG has been formed under the Chairpersonship of Dr. Rakesh Aggarwal. (First meeting was held on 2nd May'2023)
- ICMR is incorporating the data capture and multiplex testing of under-5 children with RSV, Influenza A & B and SARS-CoV-2 through its VRDL network.
- Advancing biomedical interventions for prevention of RSV disease in under-five children: India case study: Dr. Anand Krishnan.
- The burden of the RSV based on the estimates was presented.

3.2.2 Hexavalent Vaccine Working Group:

- Data on M/s Panacea Biotech's Hexavalent vaccine.
- IPV doses and schedule as requested by the MoHFW.

3.2.3 SWG-IVRCB:

- Vaccine Confidence
- Maternal Immunization
- Covid-19 Vaccine Research
- Life Course Immunization
- Capacity Building

3.2.4 Monkeypox Working Group:

- The first meeting of the working Group was held on September 9, 2022.
- The recommendations of NITAGs of other countries about the benefits and risks of monkey-pox immunization were discussed.

3.2.5 HPV Working Group: Immunogenicity data of SII' s qHPV vaccine-Cervavac®

3.2.6 NTAGI Secretariat: The NTAGI Secretariat staff may be stationed at MoHFW, ICMR, DBT/Autonomous Institutions of DBT, on rotation basis for efficient functioning of the NTAGI. A meeting in the presence of the chair & Co-chairs was held and a decision on shifting of the Secretariat from NIHFW to DHR/DBT Institution has been made.
Recruitment of all positions in the NTAGI Secretariat may be expedited: 4 technical positions and 1 administrative position have been filled. Screening of four positions is ongoing.

3.2.7 Discussion:

The Co-chairperson mentioned about the in-depth deliberations taken place with respect to rationale, doses and schedule of the hexavalent vaccine during the STSC. Dr. Arora pointed out that the program has introduced the third dose of fIPV at 9 months; the fIPV is now administered at 6 weeks, 14 weeks and 9 months. The immunogenicity with three fIPV doses is equivalent to three full doses of IPV (part of the hexavalent vaccine). Hence the group decided not to consider Hexavalent vaccine for introduction in to program at this stage.
The Co-chairperson commented that there is no licenced vaccine against RSV disease at present but RSV is an important target. The vaccine and other preventive measures (i.e. monoclonal antibodies) shall specially cater to a sub-set of population that is relatively vulnerable to infections and associated adverse outcomes, especially the preterm babies.
Dr. Rakesh Aggarwal commented that after the initial reporting of a few cases, Monkey-pox cases were not reported and the vaccine was recommended primarily for the health care workers and researchers engaged in this area. India can consider procuring and stockpiling the Monkey-pox vaccine in case of urgent requirement. Dr. Arora commented on the country's requirement of stockpiling the vaccine as well as having R&D and manufacturing facility due to Pox Virus being a Global Health threat. The co-chairperson agreed by adding

that the National Institutes of Health (NIH), USA stockpiled large volume of the vaccine to face any outbreaks; NIH institutes have the capacity to manufacture, conduct animal and human studies and the immunogenicity trials for the vaccine development which translates to obtaining an FDA approval for the newly developed vaccine. Such strategy requires resources and a R&D agenda not limited only to vaccine production of M-pox vaccine but for diseases with outbreak potential like the Nipah Virus (NiV) Disease and the Zika Virus (ZiKV).

DG-ICMR emphasized on need of a designated institute in the country to carry the tasks skilfully and strategically, avoiding ad-hoc activities.

The Chairperson suggested the NTAGI committee to consider recommending/facilitating an academic trial versus the regulatory approval for a single dose administration of the SII's qHPV vaccine, given its off-label use and introduction in to the national program. The WHO's independent expert advisory group, SAGE has also recommended the single-dose regimen of HPV vaccine in 2022 without stringent regulatory approvals. Dr. Arora added to expedite the academic proposition and suggested ICMR to lead the process and complete the study by the year 2025. It shall also provide global recognition to an indigenously develop vaccine for single-dose schedule. Dr. Rakesh Aggarwal agreed and emphasized the priority for study initiation. The DG-ICMR offered to conduct the study under the umbrella of the Indian Council of Medical Research (ICMR) along with a chosen public health agency. The suggestion was well received by the chairperson and the members of NTAGI.

The Chairperson re-iterated that the inclusion of the SEC is mandatory for regulatory trials. Following the evidence generation by the academic trial, off – label use of single dose regimen of the indigenous HPV vaccine in programmatic context is to be decided by the MoHFW, not the regulatory body. Dr. Rakesh Aggarwal highlighted that NTAGI has previously recommended the off-label use of many vaccines, the low dose intradermal polio vaccine(fIPV) was one such example.

The DG-ICMR mentioned that the ICMR is conducting a pan-India testing surveillance for RSV, Influenza and SARS-CoV-2, with some representation from children under 5 years. Inclusion of data from this age-group shall be expanded hence forth. The present study data are available on the ICMR website and can be viewed by anyone. Data is regularly shared with National Centre for Disease Control (NCDC).

With reference to the shifting of the NTAGI secretariat to any DBT/DHR institute, the chairperson commented on maintaining a strict timeline for the implementation, to which the Additional -Commissioner (AC, Immunization div.) responded that the matter would be taken up on priority.

The DG-ICMR suggested that the association of a liaison member from the DBT and the ICMR, posted on a rotational basis for coordination with the NTAGI shall be highly beneficial.

3.3 45th NTAGI-STSC Meeting: The following were discussed in the STSC meeting:

3.3.1 SWG-Vaccine Preventable Disease Surveillance:

Vaccine Preventable Diseases where WHO-SEAR modules exist, these were accepted as such, without any modification, for their use in national VPD surveillance program.

A high-level meeting to discuss the integration of the vaccine preventable disease surveillance activities may be scheduled in the presence of the Secretary (Health and Family Welfare), Secretary DHR and DG-ICMR, Secretary DBT, and DGHS. Further a meeting of all vertical programs involved in VPD surveillance may be scheduled.
As existing outbreak-based surveillance data generated by IDSP may not be sufficient to address the need of the NTAGI work, the immunization division may continue to support the VPD surveillance with additional layer required for elimination/eradication as per the broader commitments. Additionally, mechanism may be made in place for sentinel surveillance for diseases where usual surveillance may not be programmatically feasible.
The NTAGI Secretariat may be provided access to IDSP-IHIP data base.
The NTAGI should monitor and evaluate the immunization program for the report submission to WHO-SAGE.

3.3.2 Japanese Encephalitis Working Group

3.3.3 SWG-Immunization and Vaccine Research and Capacity Building

3.3.4 PCV for Sickle Cell Disease:

- Sickle Cell Disease patients should be provided with available PCV vaccine with highest valency. Catch-up vaccination for children and adolescents depending upon the age of presentation is recommended.
- Secretariat to do review evidence added advantage of PPSV in individuals who had already received three doses of PCV -10/13, and on reported hypo responsiveness with PPSV.
- Need for continued surveillance of serotypes of Pneumococci in view of expected serotype replacement.
- Evidence review on catch-up vaccination of adult SCD patients and pregnant women with SCDs need to be conducted.
- Studies on burden of invasive disease due to *S.pneumoniae,* Hib *and N.meningitidis* and other pathogens in SCD in India

3.3.5 Discussion:

The DG-ICMR opened the discussion by mentioning that recommendations of the SWG-IVRCB were debated in depth the 45th NTAGI-STSC meeting. He further added that the immunization division (MoHFW) has the mechanism to conduct the pan-India surveillance for the VPDs of interest. The NCDC, as their core responsibility, conducts surveillance for multiple VPDs across the country, the other institutes like the ICMR may be involved in the sentinel surveillance. However, there is a notable lack of Integration of the surveillance data of VPDs from different divisions and partners.
The DG-ICMR conducted a meeting with the Director General (Dte.GHS) subsequent to the 45th NTAGI-STSC meeting. It was deliberated whether the immunization division should continue with the surveillance activities of the program, granting that NCDC performs the surveillance as a major responsibility of the Institute. It would be appropriate for the program

division to carry out the surveillance for a VPD like Polio. For majority of the VPDs the Integrated Disease surveillance programme (IDSP) of the NCDC records the ongoing events, alerts, outbreaks etc. via its Integrated-Health-Information-Platform (IHIP). The DG-ICMR also had the discussion on the same agenda with Shri. Lav Agarwal, Additional Secretary (IH). Dr. Rakesh Aggarwal pointed out the difference in the quality of the surveillance data obtained from sources such the NPSP and the NCDC.

The Chairperson educated the NTAGI committee about the structure and function of the IHIP. It is a modular database capturing 33 emerging and re-emerging disease across the nation, the list maybe updated as per requirement. The ownership and operation of the IHIP is via the NCDC, on behalf of the MoHFW.

The Auxiliary Nurse Midwife (ANMs), General duty medical officers (G.D.M.O s) and the Laboratory professionals are the force behind the data capture on the IHIP and can be trained to obtain quality data, an issue that was raised by a member. The State surveillance officer and the district surveillance officer are better equipped to operate the IHIP, however this task force can be strengthened and further trained to upgrade the surveillance quality. Transmission of data between the data repositories outside IHIP into the IHIP may then also be taken up.

The DG-ICMR agreed to the same and put forth that integration between the agencies conducting the surveillance should involve the inputs of the immunization program division, as the data available for few VPDs may not hold exact relevance for the program.

The Chairperson highly encouraged a priority liaison between the program division and the IDSP (NCDC) for enhancing the surveillance datasets and cater to their decision-making process and to define timelines for the same

Dr. Arora mentioned that NTAGI can be force behind all the integration processes. It also supposed to review the immunization program and can hold the agencies involved in the integration, accountable.

The Chairperson handed over the responsibility of this imminent task to Dr. Ashok Babu (JS-RCH).

DG-ICMR highlighted that the Centre for Disease Control, Atlanta website has an integrated data reflecting at once source and our country must follow suit.

The Chairperson also added that post the integration of the surveillance systems, the program division may collect the surveillance data to validate the hypothesis or to verify the information reflected on the IHIP. The program division data would therefore be a subset of the data on the IHIP. This shall enhance the integration and negates the need for the division to conduct separate surveillance

4.0 Agenda Item 3: Covid-19 Vaccines: Chairperson, COVID-19 Working Group

Dr. N K Arora, Chairperson, shared an update on the COVID-19 Working Group (CWG). The Group was constituted in August 2020 during the COVID-19 pandemic, and 53 meetings have been conducted till date. COVID-19 was discussed in 43rd and 45th NTAGI-STSC meetings since the 17th NTAGI meeting in 2022. The Chairperson highlighted the activity of the COVID-19 Working Group, such as prioritization of beneficiaries of COVID-19 vaccines throughout

the duration of the pandemic, evidence review and guidance on preclinical and clinical trial data of COVID-19 vaccines (including newer "Make-in-India" vaccines such as intradermal mRNA vaccine, DNA vaccine, and intranasal vaccine), economic impact of vaccination, import of vaccines, and primary and precaution vaccination for beneficiaries through the Programme.

A. Recommendation on vaccines by the COVID-19 Working Group and STSC:

Six vaccines have been recommended by the COVID-19 Working Group and the STSC as heterologous booster/precaution dose – COVISHIELD™, CORBEVAX™, iNCOVACC®, GEMCOVAC®-OM, COVOVAX® and ZyCoV-D.

In addition to the above, intramuscular mRNA vaccine GEMCOVAC-19 (based on the ancestral strain of SARS-CoV-2) has been recommended as a primary series of 2 doses in adults, and COVOVAX® has been recommended in children aged 12 years and older.

All the vaccines approved by the COVID-19 Working Group and the STSC have demonstrated adequate safety and humoral and cell-mediated immunity. The BBV154 COVID-19 vaccine (iNCOVACC®) is one of the only two intranasal vaccines available in the world, and induces adequate mucosal immune response (as measured by secretory IgA) following 2-dose primary series as well as booster dose. The timing of development of several of the Indian vaccines has prevented generation of efficacy data for the vaccine. The new intranasal platform may be used to develop vaccines for other respiratory viruses, thereby interrupting transmission and making this technology a national gain. Similarly, ZyCoV-D, the only DNA COVID-19 vaccine in the world, and mRNA platform (GEMCOVAC-19 and GEMCOVAC®-OM) can be platforms for development of novel vaccines in future. The Chairperson re-iterated that Omicron specific vaccine GEMCOVAC®-OM (intradermal) which is the first of its kind (intradermal) globally, and should be considered for heterologous booster vaccination in current times in view of the global and Indian dominance of the Omicron variant of SARS-CoV-2. NTAGI recommendation for booster/precaution dose is for individuals over 60 years of age, and comorbid/immunocompromised individuals aged 18-60 years.

B. Other recommendations:

The CWG and NTAGI-STSC have recommended availability of precaution/booster doses of COVID-19 vaccines in the private sector for individuals above 18 years of age. The group also recommended that COVID-19 vaccine manufacturers should compare their immunogenicity data with that of other COVID-19 vaccines by using international standards. Also, national standards for SARS-CoV-2 immunogenicity assays should be available for access by vaccine manufacturers, in view of India's position as a global research and development hub.

It is important to harmonize the working of CDSCO- SEC and NTAGI Working Groups, and DCGI may share information related to protocols of vaccine studies with NTAGI Working Groups to facilitate the process. Results of preclinical studies should be reviewed by regulatory authorities as well as NTAGI Working Groups for COVID-19 as well as other vaccines.

The Chairperson stated that the country can now take pride in becoming a research and development hub for vaccines besides a manufacturing centre. It is important that the

regulatory ecosystem is made friendly for innovation and manufacturing while maintaining the highest standards of approval processes, so that the Indian products have global credibility and acceptability.

4.1 Discussion:

Dr. Manindra Agrawal from IIT-M wanted to share the COVID-19 modelling work done by his group and need for vaccine doses in the current scenario. The chairperson suggested that these findings may be discussed in detail within the NTAGI and its concerned Working Group. Dr. F.U Ahmed commented on the importance of COVID-19 vaccines in preventing severe disease, and queried on policies for equitable access to the vaccine. He also emphasized that the country should now have vaccination policies for adult individuals, especially with vaccines such as Human Papillomavirus Vaccine (HPV) and Pneumococcal Vaccine (PCV). Dr. Ahmed stressed on the importance of synchronization of surveillance data collected from health centres by different agencies in order to avoid discrepancy, duplication, and ensure effective integration of data at the national level. Dr. Rakesh Aggarwal mentioned that two different vaccination approaches have been adopted by countries for COVID-19 boosters. Some countries like Israel vaccinate their eligible population every 6 months. This strategy is expensive, and the benefit is definite but small. The second approach followed by several other countries focuses not on the vaccination of the eligible population, but rather on the vaccination of high-risk individuals such as those aged 75 years and above. However, this makes the booster an individual choice rather than a public health tool, and the same approach may be considered for India. Dr. Rajiv Bahl appreciated the proceedings of the COVID-19 Working Group, and solicited definite recommendations from the WG on COVID-19 vaccine booster dose. He supported Dr. Rakesh Aggarwal's comments on the vaccine booster being an individual choice, and further stated that COVID-19 vaccination need not necessarily be registered on the CoWin portal, similar to other UIP vaccines. Dr. NK Arora highlighted the importance of CoWIN platform as a national vaccine registry since it captures countrywide COVID-19 vaccination data from public as well as private setups.

He also invited Dr. Manindra Agrawal to present his study at the next meeting of the COVID-19 Working Group. He emphasized the need for accessibility to additional COVID-19 vaccine boosters in the market, allowing individuals the opportunity to choose, and availability of adequate vaccines for high-risk groups for the upcoming year or two, depending on the situation.

5.0 Agenda Item 4 : Updates on PCV for SCD : Chairperson, PCV for SCD Working Group

The earlier discussion by the co-chairperson, DG-ICMR, pertaining to the 45th STSC recommendations on the PCV for Sickle Cell Disease patients opened the floor for discussion on the Working Group. Dr. Satinder Aneja, Chairperson, PCV for SCD working group, highlighted primarily that the Globally, a polysaccharide Pneumococcal Vaccination (PPSV) in addition to the conjugate vaccine of the highest valency (PCV) is administered. PPSV offers

broader coverage of serotypes but this advantage is offset by its limited efficacy, shorter duration of protection and reported hyporesponsiveness. Therefore, a review of additional benefits and harms, if any, of PPSV is required, keeping in mind the current pneumococcal serotypes causing invasive pneumococcal disease in India. There has been a considerable replacement of the circulating serotypes of *S.pneumoniae*, especially in the countries where the PCV has been part of the program for over twenty years. Most Pneumococcal infections in patients with the Sickle cell disease are now caused by the circulating non-vaccine serotype in these countries. Therefore, continued surveillance for the prevalent serotype is essential in our country. The NTAGI also needs to formulate guidelines on the administration of the Meningococcal vaccine to the vulnerable SCD patients. The ICMR shall coordinate with the NTAGI in providing data of the circulating serotypes of the N. meningitidis to assess the disease burden in the younger age group for developing policy decisions for introducing the meningococcal vaccine. Development of similar guidelines for the adult population are planned for the future meeting of the working group.

6.0 Recommendations of the 18th NTAGI Meeting:

The Decision regarding the heterologous booster vaccination of Covid-19 to be taken by the Working Group. Current recommendations of single precaution/booster doses for individuals over 60 years of age, and comorbid/immunocompromised individuals aged 18-60 years continue.

- The COVID-19 Working Group should review scientific evidence and provide definite recommendations on the need of an additional booster dose.
- COVISHIELD™, CORBEVAX™, iNCOVACC®, GEMCOVAC®-OM, COVOVAX® and ZyCoV-D are recommended for use as heterologous boosters.
- Omicron specific vaccine GEMCOVAC®-OM should be considered for precaution/booster vaccination in present times.
- Gemcovac-19 is recommended as a primary series of 2 doses in adults, and Covovax is recommended in children aged 12 years and older.
- COVID-19 vaccines should be available in the private sector for primary schedule and single precaution/booster dose for individuals above 18 years of age.
- Dr. Manindra Agrawal is to be invited to present his modelling work in the next meeting of the COVID-19 Working Group.
- COVID-19 vaccine manufacturers should compare their immunogenicity data with that of other COVID-19 vaccines by using international standards.
- National standards for SARS-CoV-2 immunogenicity assays should be available for access by vaccine manufacturers.
- ICMR shall conduct an Immunogenicity trial on a single dose regimen of HPV vaccination in 9-15 year with suitable controls for off label use in public health settings.
- ICMR may include under-5 children for RSV surveillance in addition to influenza

- The re-location of the NTAGI Secretariat from the NIHFW to the DBT/DHR institutes maybe initiated according to a timeline.
- A priority liaison between the program division and the IDSP (NCDC) for enhancing the integration of VPD surveillance datasets with the assistance of IHIP database is to be scheduled on a timeframe.
- DCGI may share information related to protocols of vaccine studies with NTAGI Working Groups in order to harmonize the working of CDSCO SEC and NTAGI. Results of preclinical studies should be reviewed by regulatory authorities as well as NTAGI Working Groups for COVID-19 as well as other vaccines.
- It is important to develop vaccination policies for adult individuals
- Sickle Cell Disease patients should be administered the available PCV vaccine (with highest valency). Catch-up vaccination for SCD/carrier children and adolescents who are not immunized yet is recommended.
- Secretariat to do evidence review about the additional advantage of a dose of PPSV in individuals who have already completed the PCV -10/13 schedule, and on the reported hypo responsiveness with PPSV doses.
- Need for continued surveillance of serotypes of Pneumococci in view of expected serotype replacement.
- Evidence review on catch-up vaccination of adult SCD patients and pregnant women with SCDs need to be conducted.
- Studies on burden of invasive disease due to *S.pneumoniae*, Hib and *N.meningitidis* and other pathogens in SCD in India to be implemented with coordination of liaison members of the NITAG.

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18th National Technical Advisory Group on Immunization (NTAGI) Meeting
July 26, 2023, Wednesday, 02:35 P.M to 03:55 P.M
First Floor, Room No. 155-A, Nirman Bhawan, MoHFW, New Delhi

Annexure – 1

List of Participants

S.No.	Name	Designation	Attendance
Chairperson			
1.	Shri. Rajesh Bhushan	Secretary, Department of Health & Family Welfare	In-Person
Co-Chairperson			
2.	Dr. Rajiv Bahl	Secretary, Department of Health Research & DG-ICMR	In-Person
Core Members, Ex-officio			
3.	Dr. Sheela V Godbole	Director, National Institute of Virology	Virtual
4.	Dr. Jayanta Bhattacharya	Executive Director, THSTI, Faridabad	Virtual
5.	Dr. Debasisa Mohanty	Director, National Institute of Immunology	In-Person
6.	Dr. Monil Singhai	Joint Director (CAZD), NCDC	Virtual
Core Members, Independent Experts			
7.	Dr. N. K Arora	Executive Director, INCLEN Trust International	In-Person
8.	Dr. Rakesh Aggarwal	Director, JIPMER, Puducherry	In-Person
9.	Dr. Soumen Basak	Head, Systems Immunology Research Group, NII	In-Person
10.	Dr. Satinder Aneja	Former Director Professor &Head, (Dept. of Paediatrics), LHMC, Delhi	Virtual
11.	Dr. F U Ahmed	Former Director, NEIGRIHMS	Virtual
12.	Dr. Neerja Bhatla	Professor, AIIMS, New Delhi	Virtual
13.	Dr. Manindra Agrawal	Professor, IIT Kanpur	Virtual
14.	Dr. Randeep Guleria	Former Director, AIIMS, New Delhi	Virtual
15.	Dr. Jacob John	Professor, CMC Vellore	Virtual
16.	Dr. Mathew Varghese	Head of Orthopaedics, St. Stephen's Hospital, New Delhi	Virtual
17.	Dr. Nithya Gogtay	Professor, Clinical Pharmacology, SGSMC and KEM Hospital, Mumbai	Virtual
18.	Dr. R.M. Pandey	Professor and Head, Biostatistics AIIMS, New Delhi	Virtual
19.	Dr. Star Pala	Additional Professor, Community Medicine, NEIGRIHMS, Shillong	Virtual
Liaison Members			
20.	Dr. P. Ashok Babu	Joint Secretary-RCH, MoHFW	In-Person
21.	Dr. Veena Dhawan	Additional Commissioner-Immunization, MoHFW	In-Person
22.	Mr. A.K Pradhan	Joint Drugs Controller of India	Virtual
Professional Organization Representatives			
23.	Dr. G.V Basavaraja	President-Elect 2023, Indian Academy of Paediatrics	Virtual
24.	Dr. Nomeeta Shiv Gupta	Representative, Indian Medical Association	Virtual

25.	Dr. Sanjay P Zodpey	President, Public Health Foundation of India	Virtual
International Partner Representatives			
26.	Dr. Roderico H Ofrin	Country Representative, WHO, India	Virtual
27.	Mr. Luigi D'Aquino	Chief of Health, UNICEF	In-Person
State Representatives			
28.	Dr. B.R Patel	Joint Director, Child Health, Gujarat	Virtual
29.	Dr. Bijay Kumar Panigrahi	Director, Family Welfare, Odisha	Virtual
30.	Smt. Jasmine Pattnaik	Joint Secretary, Odisha	Virtual
31.	Dr. Tapas Kumar Patra	SEPIO, Odisha	Virtual
Special Invitees			
32.	Dr. Nivedita Gupta	Head, Epidemiology and Communicable Diseases (ECD), ICMR	Virtual
33.	Dr. Suhas Dhandore	Joint Director, Immunization division, MoHFW	In-Person
34.	Dr. Ashish Chakraborty	Assistant Commissioner, Immunization division, MoHFW	In-Person
35.	Dr. Shipra Verma	Sr. Consultant, Immunization division, MoHFW	In-Person
NTAGI Secretariat			
36.	Dr. Supriya Gambhir	Senior Research Scientist- Infectious Disease	In-Person
37.	Dr. Labanya Mukhopadhyay	Research Scientist – immunology	In-Person
38.	Dr. Chitrangada Mistry	Research Scientist	In-Person
39.	Dr. Dinesh Kumar	Research Analyst- Health Economics	In-Person
40.	Ms. Krittika Bhattacharyya	Research Analyst- Biostatistics	In-Person
Members Apologized			
41.	Dr. Rajesh Gokhale	Co-Chairperson, Secretary DBT	
42.	Dr. Atul Goel	DGHS, GOI and Director, NCDC	
43.	Ms. L.S Changsan	Additional Secretary & Mission Director NHM	
44.	Dr. Alka Sharma	Scientist 'H', DBT, New Delhi	
45.	Dr. Jyoti Logani	Scientist 'F', DBT, New Delhi	
46.	Dr. Lalit Dar	Professor of Virology, AIIMS, New Delhi	
47.	Dr. Surinder Jaswal	Dean (Research and Development), TISS, Mumbai	
48.	Dr. K.S James	Director, IIPS, Mumbai	
49.	Dr. Priya Abraham	Professor, CMC Vellore	
50.	Dr. Jugal Kishore	Professor and Head, Community Medicine, VMMC & SJH, New Delhi	
51.	Dr. Shankar Prinja	Additional Professor, Health Economics, PGIMER Chandigarh	
52.	Shri Sampath Kumar	PS-H&FW, Meghalaya	
53.	Dr. Maninder Kaur Dwivedi	PS-H&FW, Chhattisgarh	

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Annexure-2

Agenda

Chair: Shri. Rajesh Bhushan, Secretary (H&FW), MoHFW	***Co-Chair: Dr. Rajiv Bahl, Secretary DHR & DG-ICMR***	***Co-Chair: Dr. Rajesh Gokhale, Secretary DBT***
	General Business	NTAGI Secretariat
02:30 P.M – 02:32 P.M	Welcome and Introduction	Chairperson and Co-Chairpersons, NTAGI
	Submission of minutes of the 17th NTAGI meeting held on 28th June'2022	
Agenda no. 1: Action Taken Report		
02:32 P.M - 02:37 P.M	Action taken report on the minutes of 17th meeting of NTAGI	JS-RCH
02:37 P.M - 02:40 P.M	Discussion	NTAGI Members
Agenda no. 2: STSC Updates		
02:40 P.M - 02:50 P.M	STSC updates and recommendations	Co-Chairpersons
02:50 P.M – 02:55 P.M	Discussion	NTAGI Members
Agenda no. 3: COVID-19 Working Group (Closed Session)		
02:55 P.M - 03:05 P.M	STSC discussion and recommendations on Covid-19	Chairperson- Dr. N.K
03:05 P.M - 03:10 P.M	Discussion	NTAGI Members
Agenda no. 4: PCV for SCD (Closed Session)		
03:10 P.M – 03:20 P.M	STSC discussion and recommendations on PCV for SCD	Chairperson- Dr. Satinder Aneja
03:20 P.M - 03:25 P.M	Discussion	NTAGI Members
Agenda no. 5: Recommendations of NTAGI (Closed Session)		
03:25 P.M – 03:28 P.M	Final Recommendations of 18th NTAGI meeting	Chairperson and Co-Chairpersons
03: 28 P.M - 03:30 P.M	***Concluding Remarks***	Chairperson and Co- Chairpersons